

REMARKS

An interview concerning the instant application was conducted on February 27, 2003 with Examiner Dees of the United States Patent Office and Applicants' attorney John C. Serio. Applicants thank Examiner Dees for courtesies extended in the granting and conducting the interview. The Examiner suggested, during the interview, that prior art rejections concerning the claimed invention may be addressed by more specifically and directly emphasizing the self supporting resilient nature of Applicants' hydrogel. Applicants thank the Examiner for this suggestion.

Status of Claims

This application has been further reviewed in light of the Office Action dated November 5, 2002 and the subsequent interview on February 27, 2003. Claims 1-30 are pending in the application. By the present amendment, claims 1, 12, 23 and 28 are amended in a manner, which is believed to overcome the rejections in the Office Action.

Claims 1-22 are rejected under 35 U.S.C. §112, first paragraph.

Claims 1-22 were rejected under 35 U.S.C. §112, first paragraph. The Examiner states that the claims as pending contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. The Applicants respectfully traverse this rejection. It is respectfully suggested that both alkyl diols and polyalkyl diols are presented within the specification in the plural form and that one skilled in the art would realize that one or more of the respective compounds could be used in the instant claimed invention. The Examiner further states that the instant application lacks support for a first and second solutions comprising polyalkyl diol. Applicants have amended claim 12 to claim a second solution comprising an alkyl diol, such amendment finds full support in example A of the instant application. The Applicants respectfully request that this rejection be withdrawn.

Claims 1, 12-14 and 18-30 are rejected under 35 U.S.C. §102(b)

Claims 1, 12-14 and 18-30 are rejected under 35 U.S.C. §102(b) as being anticipated by Cartmell et al. (U.S. Patent No. 5,160,328, "Cartmell"). Applicants respectfully submit that amendments contained herein more specifically define that Applicants claimed invention as being directed to a "self supporting resilient hydrogel" and therefore further define Applicants' claimed invention so that claims 1, 12-14 and 18-30 are not anticipated by Cartmell under 35 U.S.C. §102(b).

Claim 1 has been amended to more accurately describe and emphasize Applicants' invention. The modifying term "self supporting resilient" is added to claim 1 to further indicate that the hydrogel composition made by the method of the present invention has advantageous strength and a self supporting composition that is not seen in the prior art. The hydrogel of Cartmell does not have the "self supporting resilience" of the instant application. Unlike Applicants' claimed invention, the hydrogel of Cartmell requires substrate deposition. Cartmell does not disclose (or suggest modifying the disclosure) to obtain a self supporting resilient hydrogel as claimed by the Applicants. Therefore, Applicants respectfully submit that claim 1 and all claims depending therefrom, namely claims 2-11, are not anticipated by Cartmell under 35 U.S.C. §102(b).

Claim 12 clearly defines a method of the invention for producing a "self supporting resilient" hydrogel composition. Claim 12 recites a method including a step of forming a first solution by blending a polyurethane prepolymer with a polyalkyl diol, a step of forming a second solution by combining water and an alkyl diol and an accelerator, a step of adding an additive agent to the first or second solution, and a step of combining the first solution with the second solution.

Claim 12 emphasizes the "self supporting resilient" nature of Applicants' hydrogel. Unlike the hydrogel disclosed in Cartmell, Applicants' hydrogel dressing functions without additional components such as support layers or substrates. The Cartmell hydrogel does not have sufficient strength to function without support layers or substrates, as it is required to be deposited onto a substrate for support. This need for a supported hydrogel is disclosed

throughout the drawings, description and claims of Cartmell, particularly disclosed in the Cartmell specification as follows:

“[i]t is **preferable to have a support layer** made of a polymeric film and a second support layer made from, for example, scrim adhesively secured to the support layer, both of which are interposed between the hydrogel layer and the substrate” (See Cartmell at col. 2, lns. 44 to 48, emphasis added)

Applicants respectfully submit that the method of claim 12 and the compositions produced according to the method are not disclosed or suggested in Cartmell, and accordingly are not anticipated under 35 U.S.C. §102(b).

Claims 23 and 28 have been amended to claim a “self supporting resilient hydrogel” composition having a thickness of approximately 2.0 to 2.5 cm. This thickness range is outside that found in the Cartmell patent, which discloses a composition from 0.6 to 1.5 cm thick. Furthermore, the self supporting resilient nature of Applicants’ claimed invention is not taught or suggested in Cartmell. Claims 18, 20, 22, 24, 25, 26, 27, 29 and 30 are directed to various shapes that are molded for a variety of uses. These various shapes and uses are not possible with a non-self supporting hydrogel. Applicants respectfully submit that the “self supporting resilient hydrogel” required by the shapes in the above claims is not disclosed or suggested by Cartmell.

Claim 23 has been amended to more accurately describe and emphasize Applicants’ invention. The modifying term “self supporting resilient” is added to claim 23 to further indicate that the hydrogel composition made by the method of the present disclosure has advantageous strength and a self supporting nature that is not seen or suggested in the cited references.

Applicants respectfully submit that the claimed compositions and methods of producing those compositions are not anticipated by Cartmell under 35 U.S.C. §102(b). As has been clearly enunciated by the Federal Circuit: Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. Lindermann Maschinenfabrik GMBH v. American Hoist and Derrick Co., 221 USPQ 481, 485 (Fed Cir. 1984) (emphasis added). Here the requirement of showing each and every

element of Applicant's claimed invention has not been met, as Cartmell fails to disclose or teach a hydrogel that is self supporting. It is respectfully requested that these rejections based upon 35 U.S.C. §102(b) be withdrawn.

Claims 1-11 and 12-17 are rejected under 35 U.S.C. §103(a)

Claims 1-11 and 12-17 are rejected under 35 U.S.C. §103(a) as being unpatentable over Cartmell in view of Hennink et al. (U.S. Patent No. 5,219,325, "Hennink").

Claim 1 has been amended to more directly emphasize the "self supporting resilient" hydrogel of Applicants' claimed invention. The modifying term "self supporting resilient" is more concisely claimed, further indicating that the hydrogel composition, made by the method of the present invention has advantageous strength, and therefore, does not require a substrate for support, unlike prior art hydrogels.

Claim 12 emphasizes that the "self supporting resilient" hydrogel wound dressing of the instant invention has sufficient mechanical strength to be applied to a wound without requiring support by a substrate material or support layers. Neither Cartmell nor Hennink considered alone or in combination, teach or suggest Applicants' invention including all of elements of claims 1 and 12, as amended and described above.

Furthermore, the disclosure of the present invention at page 10, line 17 to page 11, line 9 teaches the unexpectedly superior results achieved by the present invention, for instance, strength and flexibility, transparency and water absorption characteristics, all which are not achieved or suggested by Cartmell and/or Hennink.

The Examiner states that use of the agents disclosed by Hennink and Cartmell to obtain a hydrogel composition containing such agents for the purpose of controlling infection in opened wounds is obvious. However, in the instant case, neither cited reference contains a self supporting resilient hydrogel. Since the self supporting nature of the inventive hydrogel is not found in the art, it is fair to assume that in raising the obviousness rejection, the Examiner gleaned knowledge from Applicants' disclosure, contrary to well-established legal principles.

Applicants respectfully request that the rejected claims be favorably reconsidered in light of well-established legal principles, which provide,

"That one skilled in the art is not synonymous with obviousness.... That one can reconstruct and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the reference to make the claimed invention" Ex parte Levengood, 28 USPQ 2d 1300 (Bd. Pat. App. & Inter. 1993).

The particular combination of the cited references, which the Examiner makes in an attempt to arrive at the Applicants' invention, is neither taught nor suggested by either reference. The references, alone or in combination, because of each's feature differences, as discussed above, do not provide "sufficient impetus" to support the combination that the Examiner makes to effect the obviousness rejection. Furthermore, the combination that the Examiner suggests does not arrive at the Applicants' invention.

Applicants therefore respectfully submit that claim 1 and its dependant claims 2-11, and claim 12, and its dependant claims 13-17, are not obvious under 35 U.S.C. §103(a) over Cartmell in view of Hennink, and respectfully request reconsideration and withdrawal of the rejection.

A rejection was made to claims 1-30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-75 of U.S. Patent No. 6,180,132 (the '132 patent). Applicants suggest that the claimed subject matter of the rejected claims differ from that of the claims within the '132 patent. Specifically several rejected claims are directed to a variety of additives that are not found within the '132 patent. Further, other rejected claims are directed to shapes and methods of use of the self supporting hydrogel that are also not found within the '132 patent. In order to facilitate the passage of the instant application to allowance Applicants may execute an acceptable terminal disclaimer upon an indication that the present claims are allowable.

CONCLUSION

Accordingly, it is believed that in view of the above comments and further amendments to the claims, all claims are now in condition for allowance, and therefore reconsideration and allowance are earnestly solicited. If the Examiner feels that a further telephone conference would expedite allowance/issuance of this case, or resolve any remaining or other issues, the Examiner is invited to contact the undersigned at (617) 856-8145.

Please charge any deficiency as well as any other fee(s), which may become due at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 50-0369. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 50-0369 therefor.

Respectfully submitted,



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